UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JULIAN QUINONES, Individually and on Behalf of All Others Similarly Situated, Plaintiffs,	)	
v.	)	CIVIL ACTION NO. 21-10933-WGY
FREQUENCY THERAPEUTICS, INC., DAVID L. LUCCHINO, and CARL LEBEL, Defendants.	)	

YOUNG, D.J. March 29, 2023

MEMORANDUM AND ORDER

I. INTRODUCTION

Lead plaintiff Julian Quinones ("Quinones") brings a securities class action against the defendants Frequency Therapeutics, Inc. ("Frequency"), David L. Lucchino ("Lucchino"), Frequency's Chief Executive Officer, and Carl LeBel ("LeBel"), Frequency's Chief Development Officer (collectively "the Defendants"). The essence of Quinones' case is that the Defendants deceived Frequency investors into thinking that the clinical trial for a hearing loss treatment called "FX-322" was proceeding according to plan -- despite the Defendants' alleged knowledge to the contrary. Specifically,

Quinones alleges that the Defendants made fourteen false and misleading statements regarding Phase 2a of FX-322's trial in the period between October 29, 2020, and March 22, 2021, inclusive (the "Class Period").

The Defendants moved to dismiss for failure to state a claim, arguing that Quinones has failed to plead facts with particularity establishing (1) false or misleading statements, and (2) a strong inference of scienter.

After careful examination, this Court **GRANTS** the Defendants' motion to dismiss. First, Quinones has failed to allege sufficient facts to establish that twelve out of the fourteen challenged statements are false and misleading. Absent in the complaint are sufficient particularized facts showing that the Defendants had knowledge of the patients' unmet hearing deficit criteria at the time these statements were made. Moreover, several of the challenged statements are either opinion statements or statements protected by the safe harbor provision of the Private Securities Litigation Reform Act ("PSLRA"), Securities Exchange Act of 1934, § 21E(c)(1), as amended, 15 U.S.C. § 78u-5(c)(1), and they are thus not actionable.

Second, even if Quinones has alleged sufficient facts that might allow this Court to infer that not "all" subjects enrolled in the study had a meaningful word recognition deficit as

claimed by Frequency, this action must be dismissed because Quinones' scienter allegations are not made out. Contrary to what Quinones alleges, Lucchino's disposition of a small portion of his holdings following a steep increase in the price of Frequency stock is not suspicious and does not support scienter. This is especially so given that Lucchino is the only Frequency executive that is alleged to have sold stock during the Class Period. Moreover, Quinones' confidential witness' ("CW1") second-hand, unparticularized account of what an unnamed investigator supposedly told LeBel at an unspecified time cannot support a strong inference of scienter. Nor can Quinones' "core operation" argument by itself bootstrap an otherwise lacking complaint above the high pleading standard imposed by the PSLRA. Taken together, Quinones' allegations fail to articulate a cohesive theory of fraud. Therefore, the complaint does not survive the Defendants' motion to dismiss.

A. Procedural History

Pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), a two-count class action complaint for violation of the Securities Exchange Act of 1934 was initially filed on June 3, 2021 by lead plaintiff Paul Evans ("Evans"), individually and on behalf of others similarly situated, against Frequency and Lucchino. Class Action Compl. ("Orig. Compl."), ECF No. 1. Evans and the class members alleged a violation of Section 10(b)

of the Securities Exchange Act and Rule 10b-5 promulgated thereunder (count one) and a violation of Section 20(a) of the Securities Exchange Act (count two). Id. ¶¶ 46-60.

The Court subsequently consolidated this matter with a nearly identical class action against Frequency and Lucchino, Case No. 1:21-cv-11040-WGY, Micheal Hingston, Individually and on Behalf of All Others Similarly Situated v. Frequency Therapeutics, Inc. and David L. Lucchino (D. Mass. June 22, 2021). See Order of Consolidation, March 21, 2022, ECF No. 28. Julian Quinones was appointed as lead plaintiff for the class. See Elec. Clerk's Notes, March 15, 2022, ECF No. 27.

On May 16, 2022, Quinones filed a consolidated class action complaint -- containing the same two counts as the original complaint -- against Frequency, Lucchino, and Lebel. Consol. Class Action Compl. ("Compl."), ECF No. 29; id. ¶¶ 104-18. Approximately two months later, the Defendants filed a 12(b)(6) motion to dismiss both counts of the consolidated complaint, Defs.' Mot. Dismiss Consol. Class Action Compl. ("Defs.' Mot."), ECF No. 34, and the parties fully briefed the issue, Mem. Law Supp. Defs.' Mot. Dismiss Consol. Class Action Compl. ("Defs.' Mem."), ECF No. 35; Opp'n Mot. Dismiss Consol. Class Action Compl. ("Pls.' Opp'n"), ECF No. 41; Reply Br. Supp. Defs.' Mot. Dismiss Consol. Class Action Compl. ("Defs.' Reply"), ECF No. 42.

This Court has federal question subject matter jurisdiction pursuant to section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331. Venue is proper in this district pursuant to section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b).

B. Factual Background

Quinones alleges that the Defendants -- specifically Lucchino and Lebel acting in their capacity as Frequency executives -- made fourteen separate false, misleading, incomplete, or inaccurate statements throughout the class period between October 29, 2020, and March 22, 2021, inclusive (the "Class Period"), related to a clinical trial for the company's key product that were purportedly deceiving to investors. Compl. ¶¶ 67-79. The crux of Quinones' allegations relates to one of the criteria for admission to the clinical trial: the requirement that all study participants have some form of hearing loss. Id. ¶¶ 5, 13, 36, 47, 68, 69, 73, 75, 77, 79, 86. Specifically, Frequency conveyed to investors that "all subjects" in the clinical trial "have meaningful word recognition deficits." Id. Quinones alleges that Lucchino and Lebel knew this was not the case. Id. ¶¶ 105-118. Quinones therefore claims that the challenged statements are false or misleading and, when combined with the strong inference of scienter created by, inter alia, Lucchino's increase in stock

sales during the Class Period, thus constitute a violation of § 10(b) and § 20(a) of the Securities and Exchange Act of 1934. Id. ¶¶ 105-118.

1. The Parties

Frequency is a publicly traded clinical-stage biotechnology start-up. Compl. ¶ 2; Defs.' Mem. 2. Lucchino, co-founded Frequency in 2014. Defs.' Mem. 2. Lucchino is the company's President and Chief Executive Officer. Compl. ¶ 24. LeBel has been the company's Chief Development Officer since 2018. Id. ¶ 25.

The plaintiffs are a class of shareholders who purportedly purchased Frequency's common stock at artificially inflated prices between October 29, 2020, and March 22, 2021, inclusive Id. ¶¶ 1, 22. Quinones claims they were harmed by the false, misleading, incomplete, or inaccurate statements made by Lucchino and Lebel throughout the Class Period. Id. These false or misleading statements ostensibly deceived Quinones into thinking that the FX-322 trial was proceeding according to plan -- despite the Defendant's alleged knowledge to the contrary. Id. ¶¶ 22, 80-87. Quinones alleges that they would not have purchased or otherwise acquired Frequency's stock if Defendants revealed that the study was methodologically flawed. Id. ¶ 110.

2. FX-322 Clinical Trial

Frequency was founded to develop a hearing loss treatment called FX-322, promoted as a potential treatment for patients with severe sensorineural hearing loss ("SNHL"). Id. ¶¶ 2, 28. Frequency announced promising safety and efficacy results after the first phase of the FX-322 clinical trial (Phase 1), but this study did not have enough patients fully to evaluate the effects of FX-322 on hearing loss. Id. ¶¶ 3, 31-32. Frequency announced the launch of a Phase 2a trial of FX-322 in October 2019 further to evaluate the efficacy of FX-322 as a treatment for SHNL. Id. ¶¶ 4, 35. The Phase 2a trial of FX-322 ran from September 2020 to December 2020, with study participants receiving weekly injections of either FX-322 or a placebo. Id. ¶ 8, 9. Trial participants were tracked weekly after the first injection. Id. ¶ 8.

Ultimately, Phase 2a was "unlikely to deliver results that could support the efficacy of the FX-322". Compl. ¶ 66. Frequency revealed the disappointing results of the study on the morning of March 23, 2021:

> The interim results [of Phase 2a] show that four weekly injections in subjects with mild to moderately sever [sic] [SNHL] **did not demonstrate improvements in hearings measures versus placebo.** . . . The Phase 2a interim results also showed an unexpected apparent level of hearing benefit in the placebo group that did not occur in previous trials and exceeded well-established published standards, potentially suggesting bias due to trial design. Given these

> challenges observed in the Phase 2a study design, **there was no discernible benefit of FX-322 over placebo.**

Compl. ¶ 80 (emphasis added).

The market did not react well to these disappointing results and investors -- including Quinones -- took a beating: Frequency's common stock plummeted from a share price of $36.29 at the close of trading on March 22, 2021, to $7.99 at the close of trading on March 23, 2021, a 78% drop that erased nearly a billion dollars from Frequency's market capitalization. Id. ¶ 84. Stock analysts directly attributed this precipitous decline to the revelation that Phase 2a was potentially "bias[ed] due to trial design," and one analyst noted that "management makes it sound like patients may have been faking worse hearing than they actually had to make sure they could enroll." Id. ¶ 85.

3. Timeline of Statements by the Defendants

Quinones alleges that fourteen separate statements made by Lucchino and Lebel throughout the Class Period were false, misleading, incomplete, or inaccurate in violation of 10(b). Compl. ¶¶ 67-79; see also Decl. Kevin M. McDonough Supp. Defs.' Mot. Dismiss, Ex. 2, Appendix of Challenged Statements, ECF No. 36-2. Most important among these is Lucchino and Lebel's repeated representation that the FX-322 Phase 2a trial was conducted on an unbiased and appropriate sample population -- specifically that all participants "[had] meaningful word

recognition deficits." Compl. ¶¶ 5, 13, 36, 47, 68, 69, 73, 75, 77, 79, 86. Quinones alleges this was known to be untrue and that the statements by Lucchino and Lebel were thus false, misleading, incomplete, and/or inaccurate in violation of 10(b). Id. ¶¶ 66-79, 105-118. The following table summarizes the most relevant statements throughout the Class Period, each touched on in more detail below.

Statement	**Date**
"[A]ll subjects [in Phase 2a] have meaningful word-recognition deficits." Id. ¶ 68.	10/29/2020
"[A]ll subjects [in Phase 2a] have meaningful word recognition deficits." Id. ¶ 76.	01/11/2021
Phase 2a's "[e]ntrance criteria required all subjects have meaningful word recognition deficits." Id. ¶ 76.	01/11/2021
"Every subject has to have a deficit. Now we have not disclosed what the deficit is to minimize any bias from patients but everyone has to fall within a certain range in order to qualify for the study. Id. ¶ 78 (emphasis removed).	01/19/2021

a. October 2020

The Class Period began on October 29, 2020, when Frequency issued a press release entitled "Frequency Therapeutics Announces Expanded FX-322 Clinical Development and Upcoming Day-90 Phase 2a Analysis" and posted a corporate slide presentation to the company website. Compl. ¶ 67. The press release stated,

inter alia, that all patients in Phase 2a had "mild to moderately severe acquired SNHL." Id. The corporate slide presentation also stated that, in Phase 2a, "all subjects have meaningful word recognition deficits." Id. ¶ 68 (emphasis added). Quinones alleges that this statement was materially false, misleading, incomplete, or inaccurate, because, as Lucchino and Lebel knew or recklessly disregarded, not all Phase 2a enrolled patients met the study's inclusion criteria of having a meaningful word recognition deficit. Id. ¶ 69.

b. January 2021

On January 11, 2021, after the Phase 2a clinical trial had ended, the Defendants once again stated unequivocally in a slide presentation -- posted to the company website and also filed with the SEC via Form 8-K -- that "[a]ll subjects [in Phase 2a] have meaningful word recognition deficits" and that Phase 2a's "[e]ntrance criteria required all subjects have meaningful word recognition deficits." Id. ¶ 76 (emphasis added). Lebel reiterated this requirement the next week at an investor presentation attended by Lucchino and others:

> [I]n the phase 1 safety study, there was not a requirement for anybody to fall within a range of word recognition. . . . In the phase 2A study, we've modified that. Every subject has to have a deficit. Now we have not disclosed what that deficit is to minimize any bias from the patients but everybody has

> to fall within a certain range in order to qualify for the study.

Id. ¶ 78 (emphasis added). Like the similar statements from October, Quinones alleges that these January statements were materially false, misleading, incomplete, or inaccurate, because, as Lucchino and Lebel knew or recklessly disregarded, not all Phase 2a enrolled patients met the study's inclusion criteria. Id. ¶ 79.

4. Support for Statements Being Misleading

a. Information From Confidential Witness

Quinones' confidential witness, CW1, was the Senior Manager of Clinical Operations at Frequency from January 2018 to September 2021. Id. ¶ 11. CW1 worked with Lebel and others at Frequency to develop the design of the FX-322 Phase 2a clinical trial, which according to Quinones, made them well-situated to have inside information regarding Phase 2a -- particularly regarding the sample population. Id. CW1 also oversaw the implementation of Phase 2a once the clinical trial began. Id. CW1 claims to have "confirmed that multiple patients enrolled in Phase 2a had qualified for and participated in the study despite not having met the inclusion criteria for the study" and that "such individuals simply 'faked being deaf' in order to enroll in Phase 2A." Id. Additionally, CW1 "revealed that during the class period, [Lucchino and Lebel] were well aware that the

Phase 2a's inclusion and exclusion criteria . . . were being disseminated online . . . ." Id.

CW1 also claims that multiple "investigators" (i.e. the doctors who administered the Phase 2a clinical trial) came forward with concerns about a discrepancy regarding the patients' ability to hear sounds at varying decibel levels. Id. ¶ 12. CW1 claims that several investigators contacted Lebel directly to express their concerns about these discrepancies. Id.

b. Blog Posts

In addition to guaranteeing that all participants in the FX-322 Phase 2a trial had meaningful hearing deficits, the Defendants repeatedly represented that the criteria for admission to the study were not publicly disclosed. Id. ¶¶ 67-79. Quinones alleges these statements are undercut by a plethora of blog posts on numerous online message boards, which, inter alia, specifically reference the hearing deficit threshold (85% or less word score recognition) that was purportedly not publicly disclosed. Id. ¶ 51-55. For example, one forum, "Tinnitus Talk,"[1] has an entire message board related to FX-322,

[1] Tinnitus is symptom of an underlying issue with the auditory system and commonly presents as a ringing in one or both ears but can also sound like roaring, clicking, hissing, or buzzing. See Compl. ¶ 49.

including the Phase 2a trial. Id. ¶ 51. As of July 2020, the FX-322 thread had over 9,000 posts and the thread is nearly 650 pages long. Id. Quinones alleges that those suffering from tinnitus believed FX-322 was a viable treatment option, based at least in part on comments made by Lebel,[2] and that, as a result, those seeking treatment for tinnitus infiltrated the Phase 2a trial despite not actually having a meaningful hearing deficit. Id. ¶ 48.

c. Lucchino's Stock Sales

Finally, Quinones claims that the rate of Lucchino's stock sales increased throughout the Class Period and increased dramatically in December 2020 when phase 2A of the FX-322 study concluded. Compl. ¶¶ 13-14. During the Class Period, Lucchino sold an average of 57,000 shares per month, an average significantly higher than the average monthly stock sales prior

[2] In July 2020, LeBel was interviewed on a podcast called "Tinnitus Talk" (which is related to the online forum). Lebel was asked whether there were "any anecdotes or patient testimonials that kind of corroborate" that FX-322 "might have a profound effect on tinnitus." He responded: "[W]e don't have data. Certainly there is anecdotal reports as patients have come back and visited with ENTs when they have had conversations with them about how they are doing. Some of them have offered that they have had improvements in tinnitus, there's nothing that we can quantitate there. Again, it adds to the excitement of the opportunity" of FX-322. See Compl. ¶ 50.

to the start of the Class Period of only 15,000 shares per month. Id.

II. ANALYSIS

The Defendants seek to dismiss Quinones' federal securities action against them on two grounds: (1) Quinones has failed to plead facts establishing a false or misleading statement, and (2) Quinones has failed to plead facts to establish a "strong" inference of scienter. Defs.' Mem. 6-20.

This Court concludes that Quinones has failed to plead sufficient facts to survive dismissal on either ground.

A. Standard of Review

To withstand a motion to dismiss, a complaint must "state a claim upon which relief can be granted . . . ." Fed. R. Civ. P. 12(b)(6). The complaint must include sufficient factual allegations that, accepted as true, "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Courts "draw every reasonable inference" in favor of the plaintiff, Berezin v. Regency Sav. Bank, 234 F.3d 68, 70 (1st Cir. 2000), but they disregard statements that "merely offer legal conclusions couched as fact or threadbare recitals of the elements of a cause of action," Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 12 (1st Cir. 2011) (brackets, ellipsis, and quotations omitted).

To plead a viable cause of action under Section 10(b)-5 of the Securities Exchange Act of 1934, plaintiffs must plead: "(1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Hill v. Gozani, 638 F.3d 40, 55 (1st Cir. 2011). In the present case only the first two elements are at issue.

B. Two Statements Could Be False and Misleading

Quinones challenges statements made by the Defendants regarding the Phase 2a trial on four different dates between October 29, 2020, and January 19, 2021. See Compl. Only two of the challenged statements meet the false and misleading thresholds but ultimately fail to survive the Defendants' motion to dismiss on the scienter requirement.

Quinones uses the same claim for each of the statements made by the Defendants, stating that they were materially false, misleading, incomplete and inaccurate because the Defendants knew, or recklessly disregarded and failed to disclose that the inclusion criteria set out for the Phase 2a trial was not being met by some patients who had faked their way in the recognition screening tests, thus jeopardizing the trial results because of bias. Compl. ¶ 69, 73, 75, 77, 79.

The Defendants argue that Quinones: (i) fails to allege the challenged statements were incorrect, (ii) fails to plead that the Defendant's forward-looking statements are actionable and (iii) fails to challenge one of the statements made by the Defendants because of the well-settled law regarding "puffery". Defs.' Mem 6-13.

To survive a motion to dismiss, plaintiffs "must show 'that defendants made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading.'" Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 454 (1st Cir. 2017) (quoting Geffon v. Micrion Corp., 249 F.3d 29, 34 (1st Cir. 2001)). A securities plaintiff is also required to "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." Id. at 455 (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008)) . The First Circuit, has further stated that "although "the PSLRA does not require plaintiffs to plead evidence . . . a significant amount of 'meat' is needed on the 'bones' of the complaint."" Id. at 455 (quoting Hill, 638 F.3d at 56). If a plaintiff's allegation regarding the statement or omission "is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." Hill, 638 F.3d at 55 (citing 15 U.S.C. § 78u-4(b)(1)).

Falsity under the PSLRA can be pled for an untrue statement of a material fact. Mississippi Pub. Emps.' Ret. Sys. v. Boston Scientific Corp., 523 F.3d 75, 85 (1st Cir. 2008) (quoting 15 U.S.C. § 78u-4(b)(1)(A)). Also, under the PSLRA "a misleading statement or omission is alleged when plaintiff claims that defendant […] 'omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading'." Id. (quoting 15 U.S.C. § 78u-4(b)(1)(B)). Information is material if a "reasonable investor would have viewed it as having significantly altered the total mix of information made available." Id. (internal quotation marks and citation omitted). "[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor." Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund, 575 U.S. 175, 186 (2015).

1. The Statements Concerning the Patients' Word-Recognition Deficit Might Be False and Misleading

This Court concludes that two statements could be found untrue and misleading, but ultimately fail to pass the PSLRA pleading standard because they lack evidence of scienter when made.

On both October 28, 2020, and January 11, 2021, Frequency represented that "[a]ll subjects have meaningful word

recognition deficits". Compl. ¶¶ 68, 76. Quinones argues that this statement is materially false, misleading, incomplete, and inaccurate because it conveyed that all subjects enrolled in Phase 2a had "meaningful word recognition deficits", when, in reality, as the Defendants knew or recklessly disregarded, this was not the case because Phase 2a enrolled patients that did not actually meet the study's inclusion criteria. Compl. ¶ 69, 77. On the contrary, the Defendants point out, that Quinones pleads no facts that show any of the patients who enrolled in Phase 2a actually faked their word recognition screening, and even had Quinones done so, he has not alleged that the Defendants could have known and disclosed the facts at the time the statements were made. Defs.' Mem. 8.

To state a plausible claim, Quinones must show that "defendants made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading.'" Ganem, 845 F.3d 447 at 454 (quoting Geffon, 249 F.3d at 34). For this reason, this Court first analyzes the material information in this statement, and then if the statement was untrue or misleading.

Phase 2a trial's success was in large part dependent on the hearing deficiency of the patients. As stated before, material information is that which a "reasonable investor would have viewed [...] as having significantly altered the total mix of

information made available." Mississippi Pub. Emps.' Ret. Sys., 523 F.3d at 85 (internal quotation marks and citation omitted). Therefore, information regarding the patients' hearing deficiency is material in this case. This is confirmed by the fact that Frequency informed their investors they had modified the trial design to keep from the public the minimum deficiency required to be part of the trial, so as to avoid bias. Compl. ¶ 78. Also, in March 2021, Frequency informed investors that the trial had finally failed because of a possible bias in the trial design. Id. at ¶ 80.

These statements claiming that "[a]ll subjects have meaningful word recognition deficits", Compl. ¶¶ 68, 76, could well be untrue. On June 30, 2021, several months after the trial had ended, and after the statement in March 2021 that informed the trial had ended unfavorably, Frequency released the final results from Phase 2a as part of an investor presentation that was filed with the SEC on Form 8-K, which included, among other statements, the following:

> Another observation of potential bias was also seen in inconsistent efforts by subjects in completing WR tests. Specifically, subjects could forego responding to test words in order to have a WR deficit at baseline. **For example, one placebo subject, had 22 "no responses" on a 50 WR test given to the patient at baseline, while only 3 "no responses" were provided at the day-90 WR test.**

Compl. ¶ 86 (emphasis added).

This passage suggests that at least one of the patients enrolled in the study did not possess the required word-recognition deficit. On this basis, drawing all the inferences in favor of Quinones, this Court could conclude that the statements that all subjects enrolled in Phase 2a had "meaningful word recognition deficits" could be untrue, and therefore misleading. This Court need not, however, make that finding. To plead a viable cause of action under section 10(b)-5 of the Securities Exchange Act of 1934, Quinones must plead a "strong" inference of scienter. As is analyzed below, Quinones has failed to do so. See infra section II.C. Therefore, the complaint does not survive the Defendants' motion to dismiss.

2. The Remaining Statements Are Not False and Misleading

a. The Statements Concerning Enrollment Criteria Are Not False and Misleading

The Defendants first claim that Quinones has not adequately challenged the accuracy of the following alleged misstatements:

> "(i) the 'Phase 2a study completed enrollment with 95 patients in September 2020, […]'; (ii) 'the Phase 2a study is a double-blind, placebo-controlled, single and repeat dose study of FX-322 in patients aged 18 to 65 with mild to moderately severe acquired SNHL, […]'; (iii) Frequency was 'expanding its FX-322 development program to evaluate FX-322's clinical profile in other SNHL patient types,' […]; (iv) the study's objectives were to 'evaluate the potential of FX-322 to improve hearing clarity or intelligibility as measured by improvements in tests of word recognition (WR) or words-in-noise (WIN),'[…]; and (v) Phase 2a's

> '[e]ntrance criteria required all subjects have meaningful word recognition deficits,' […]."

Defs.' Mot. 6 (citations omitted).

The Defendants argue that Quinones' complaint did not offer "facts showing that any of these statements were false -- that the entrance criteria or trial design, strategy, or objectives were other than as-disclosed […]". Id. at 6-7. The Court agrees with the Defendants. As the Defendants have stated in their motion to dismiss, to establish falsity, a plaintiff must allege that the challenged statements are inaccurate. Defs.' Mot. 7 (citing In re iRobot Corp. Sec. Litig., 527 F. Supp. 3d 124, 133 (D. Mass. 2021) (Casper, J). Quinones has not only failed to allege that the enrollment criteria was anything different from what the Defendants disclosed, but also expressly claimed that "[i]n sum, [the] Defendants' statements were misleading regardless of their purported accuracy." Pls.' Opp'n 7. Therefore, based on the facts alleged by Quinones, and their own admission, a claim on these statements being misleading because of falsity cannot be accepted.

Quinones also challenges as false the statement "we have not disclosed what [the word recognition] deficit is to minimize any bias [,]" Defs.' Mot. 8, n.4, to which Defendants respond that "no facts establish that the score discussed on the message board was the one used in Phase 2a, much less that Defendants

disclosed it." Id. This Court agrees. Quinones has not alleged that the Defendants were the ones to disclose the deficit required for the trial, therefore the statement in question is true.

Quinones further argues that "[the] Defendants omitted material facts necessary in order to make the statements made not misleading." Pls.' Opp'n 7 (citing Ganem, 845 F.3d at 454). Quinones defends by arguing that "it may have been literally true that Phase 2a "required all subjects to have meaningful word recognition deficits," but it is still misleading because the criteria and requirements [of the Phase 2a trial] were violated". Id.

The Defendants allege that Quinones' contention that the statements were misleading because the Defendants "allegedly omitted that some enrollees in the Phase 2a trial faked their word recognition screening tests and thus doomed the trial," Defs.' Mem. 7, fails for two reasons: (i) Quinones did not plead particularized facts showing that any patients who enrolled in Phase 2a actually faked their word recognition screening tests, and (ii), even if they did so, Quinones fails to show that the Defendants could have known and therefore should have disclosed such information. Id. 7-8. Defs.' Reply 3. The Defendants are correct. Quinones has failed to allege particularized facts

because the alleged facts do not address how and why these specific statements were misleading at the time they were made.

The "mere possession of material, nonpublic information does not create a duty to disclose it," Ganem, 845 F.3d at 454 (quoting Hill, 638 F.3d at 57 (internal punctuation omitted)), but "when a company speaks, it cannot omit any facts 'necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.'" Id.

Quinones, relying on In re A123 Sys., Inc. Sec. Litig., claims that in their complaint they have offered "factual allegations that would support a reasonable inference that adverse circumstances existed at the time . . . and were known and deliberately or recklessly disregarded by defendants." Pls.' Opp'n 9 (quoting In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d 278, 283 (D. Mass. 2013) (Stearns, J.)). Their claim that the "Defendants knew that Phase 2a was biased by patients who had intentionally 'faked' their test results", id., "'by at least October 29, 2020", id. (quoting Compl. ¶ 89), is supported by two facts disclosed by their confidential witness, CW1: (i) the Defendants "learned about bias in Phase 2a in part from online posts discussing Phase 2a's particular enrollment criteria", which was corroborated by Quinones by "identifying a post from February 13, 2020, where the existences of Phase 2a's word-recognition requirement was disclosed along with study's

maximum required word recognition score", id.; and (ii) the "Defendants separately learned about Phase 2a's bias straight from the study's investigators, who directly observed concerning discrepancies." Id. at 10 (citing Compl. ¶ 65).

Quinones further claims that the timing of all the events involved is critical because patients were tracked weekly. Id. Enrollment of patients began in October 2019 and was completed by September 2020. Id. "[T]hen most of the investigators' word recognition tests must have been completed before October 29, 2020," and "reasonable inference based upon these facts is that Defendants knew of the bias in Phase 2a by at least October 29, 2020, when the first alleged misrepresentation occurred." Id.

Even when this Court at this stage must draw all reasonable inferences in favor of the plaintiff, Berezin, 234 F.3d 68 at 70, the allegations in the complaint must meet the standard under Fed. R. Civ. P. 9(b) and the "heightened pleading requirements" imposed on private securities litigation, Mississippi Pub. Emp.s', 523 F.3d at 85, which Quinones fails to do.

CW1's statements are insufficient to reasonably infer that the Defendants, when making the alleged misleading statements, knew that enrolled patients did not actually meet the study's inclusion criteria. Therefore, it cannot be reasonably inferred from the facts alleged in the complaint that the Defendants

intentionally omitted the information, or even recklessly disregarded it. See In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d at 283 (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 198 (1st Cir. 1999)). The heightened pleading standard established for these types of cases requires not only "merely simple, or even inexcusable, negligence", but at least reckless disregard. Id.

CW1's allegations that the Defendants knew of patients that did not meet the enrollment criteria are all his own inferences, and do not meet the heightened pleading standard required for these cases. Quinones states in the complaint that CW1 worked with LeBel, overseeing the implementation of Phase 2a on behalf of Frequency, and "confirmed that multiple patients enrolled in Phase 2a had qualified for and participated in the study despite not having met the inclusion criteria for the study." Compl. ¶ 11. Yet there is no allegation that CW1 ever communicated anything he knew about test defects to the Defendants that there had been patients who had enrolled in the study despite not possessing the required word recognition deficit. See Compl. ¶¶ 11, 12. Moreover, CW1 does not give a specific date when the Defendants gained knowledge of the fact that patients had faked their word recognition screening tests, and that this was affecting the ongoing trial. Wasson v. LogMeIn, Inc., 496 F. Supp. 3d 612, 629 (D. Mass. 2020)(Burroughs, J.) (although

confidential witnesses all state that prices were raised for customer, they do not state when those price increases occurred). Nor the "concerns" raised by the unnamed "investigators" suffice to establish that the Defendants knew that one or more patients had "fake their way" into the study. See infra (C.)(2.). Even if there was information in the company that patients were not meeting the enrollment criteria, from the facts alleged it is not reasonable to infer the Defendants' knowledge.

As to the alleged blog posts that supposedly disclosed the word recognition scores for the enrollment test, even with Quinones confirming that the posts are from early 2020, it is merely speculation that the Defendants knew about the posts at that time and then disregarded them when making the statements. Meyer v. Biopure Corp., 221 F. Supp. 2d 195, 206 (D. Mass. 2002) (Harrington, J.) ("[T]he Court cannot speculate that, because former consultants themselves experienced problems, [the company's] executives must have had knowledge of the problems in compiling the data and fraudulently concealed them.").

For the above reasons, Quinones has "failed to plead with particularity facts establishing the falsity of" the statements regarding the trial's entrance criteria, and they cannot be deemed untrue. Guerra v. Teradyne Inc., No. 01-cv-11789, 2004 WL 1467065, at *8 (D. Mass. Jan. 16, 2004) (Dein, M.J.). Nor

can they be deemed misleading. Quinones does not allege facts sufficient to demonstrate that the Defendants had knowledge of the patient's unmet hearing deficit criteria at the time these statements were made. Therefore, even had the entrance criteria leaked, there are not enough facts alleged to demonstrate that the Defendants knew or recklessly disregarded the breach when making their statements, so as to consider them misleading. In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d at 283 (quoting Greebel, 194 F.3d at 198).

b. The Private Securities Litigation Reform Act's Safe Harbor Provision Applies to the Forward-Looking Statements

The Defendants argue that the challenged statements on the press releases dated October 29, 2020, and November 16, 2020, and those on the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 16, 2020, cannot be actionable false statements because they are "textbook examples of 'forward-looking statements', immunized from liability under the PSLRA 'safe harbor' . . . .." Defs.' Mem. 10. The Defendants further contend that Quinones fails to make a showing (i) that the statements either lacked any meaningful cautionary language, or (ii) that the Defendants had actual knowledge ("actually knew") that the statements were false when made. Id. at 10-11.

Quinones does not deny that the statements are forward-looking. Quinones does claim, however, that these statements are not protected under the PSLRA safe harbor because "(i) their risk warnings were inadequate, (ii) the [complaint] alleges [the] Defendants knew of the bias in Phase 2a before the statements were made, and (iii) omissions of existing facts are not protected by the PSLRA safe harbor." Pls.' Opp'n 12.

Under the safe harbor provision, a person shall not be liable with respect to any "forward-looking statements when not made with knowledge of falsity or when the statement itself is identified as forward-looking and is accompanied by 'meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement.'" Hill, 638 F.3d at 54 (quoting 15 U.S.C. § 78u-5(c)(1)(A)(i)).

The forward-looking statements in the press releases dated October 29, 2020, and November 16, 2020, and those in the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 16, 2020 include cautionary language as required under the PSLRA "safe harbor". See 15 U.S.C. § 78u-5(c)(1). Quinones describes the cautions as vague and boilerplate disclaimers, and therefore insufficient. Pls.' Opp'n 13 (citing In re Sepracor, Inc. Sec. Litig., 308 F. Supp. 2d 20, 34 (D. Mass. 2004) (Lasker, J.)). The Defendants,

however, assert the cautionary language "warned of exactly the risks that [Quinones] says materialized." Defs.' Reply 5. Determining the sufficiency of the cautionary language is not an easy duty. Quinones cites to Sepracor, where the disclaimer language was ruled insufficient because the information omitted was of relevance to the studies, more than a "bump in the road", and therefore "[d]efendants would have been obliged under the circumstances to disclose known facts about the animal studies that undermined their predictions of [the company's] success." In re Sepracor, Inc. Sec. Litig., 308 F. Supp. 2d at 34.

Here, it is the second aspect of these statements that is dispositive. Only if, when the statements were made, the Defendants knew of the existence of bias in the trial and omitted that material information, would the statements be unprotected by the PSLRA safe harbor. As analyzed above, see supra Section II.B.2.1, Quinones has failed to allege particularized facts that allow this Court reasonably to infer under the PSLRA standard that the Defendants knew of patients faking their hearing condition to be enrolled in the trial, and so had actual knowledge that the statements they were making were false. Thus, as the Defendants rightly contend, these statements are protected by the safe harbor provision, and are not actionable.

c. The Defendant's Opinion Statements Are Not Actionable

In their final argument, the Defendants argue that statements including language such as "we expect that" and that the data "will enable us" are statements of opinion that under Omnicare, are not actionable. Defs.' Mem. 11-12 (citing Omnicare, Inc., 575 U.S. at 186).

Quinones counters that the statements with this particular language are not opinion statements shielded by Omnicare. Pls.' Opp'n 11. Quinones' main argument is based on the contention that the Defendants knew of the trial's bias, and deliberately omitted this material information. See Id. at 11-12. As already discussed above at length, see supra Section II.B.2.1, this contention fails.

C. The Scienter Allegations Are Not Made Out

To be actionable under the PSLRA, a statement must be more than merely material and misleading; it also must have been made with the requisite scienter. ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46 (1st Cir. 2008). As this Court recently recalled in Sharp, Congress has heightened the pleading standard for scienter allegations in private enforcement actions. S.E.C. v. Sharp, 2022 WL 4085676 (D. Mass. 2022) (citing Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit, 547 U.S. 71, 81 (2006). The reasons underlying this important legislative intervention

were described in Galileo:

> In particular, Congress sought to reform private securities litigation to discourage unmeritorious class actions, including actions brought because of a decline in stock prices. The aims of the PSLRA are three-fold: (1) to encourage the voluntary disclosure of information by corporate issuers; (2) to empower investors so that they—not their lawyers—exercise primary control over private securities litigation; and (3) to encourage plaintiffs' lawyers to pursue valid claims and Defendants to fight abusive claims. The PSLRA seeks to curtail the filing of abusive lawsuits at the pleading stage of litigation by establishing uniform and stringent pleading requirements.

In re Galileo Corp. S'holders Litig., 127 F. Supp. 2d 251, 260 (D. Mass. 2001) (Lindsay, J.).

Specifically, the pleaded facts must give rise to a "strong" inference of scienter. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007). This means that the complaint must "with respect to each act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A); see also In re Boston Scientific Corp. Secs. Litig., 686 F.3d at30. "It does not suffice that a reasonable factfinder plausibly could infer from the complaint's allegations the requisite state of mind." Tellabs, 551 U.S. at 314. Instead, the inference of scienter must be "cogent and at least as compelling as any other opposing inference of nonfraudulent intent." Id. at 328.

Quinones maintains that the facts alleged in their complaint raise a "strong" inference of scienter. Specifically, Quinones argues that (1) Lucchino's stock sales, (2) CW1's statements, and (3) FX-322's importance for Frequency establish that the Defendants knew that not all study subjects had meaningful hearing loss. Quinones also asserts that (4) the culpable inference is at least as compelling as the non-fraudulent one. See generally Pls.' Opp'n.

After careful consideration, this Court rejects all Quinones' scienter allegations in the same order they were presented.

1. Lucchino's Stock Sales Do Not Raise a Strong Inference of Scienter

Quinones contends that Lucchino's stock sales are suspicious in amount and timing, and hence they support a strong inference of scienter. Compl. ¶ 90. Not so. If assessed in the proper context, Lucchino's disposition of a small portion of his Frequency holdings at an unsuspicious time is insufficient to raise an inference of scienter. This is especially so given that Lucchino is the only Frequency executive that is alleged to have sold stock during the Class Period. Therefore, this Court cannot infer scienter from Lucchino's stock sales. See Tharp v. Acacia Commc'ns, Inc., 321 F. Supp. 3d 206, 229 (D. Mass. 2018)((citing Lirette v. Shiva Corp., 27 F. Supp. 2d 268, 283

(D. Mass. 1998) (requiring a securities plaintiff to show that "sales by insiders were in fact unusual or suspicious in amount or timing.")).

As to the amount of Lucchino's stock sales, the gist of Quinones' argument is that Lucchino suspiciously intensified his trading activity during the Class Period from 15,000 to 57,000 shares per month, generating a total profit exceeding $9,000,000. Compl. ¶¶ 14-15. If appraised in the proper context, however, these numbers are far from suspicious.

To begin, Quinones' argument ignores that Lucchino's sales were accompanied by a similarly intensified volume of acquisitions, which courts have consistently ruled undercuts an inference of scienter. Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228, 246 (1st Cir. 2015)(holding that an individual defendant's purchase of company stock during the class period "negates any inference that he had a motive to artificially inflate [the company's] stock during that period."); Mehta v. Ocular Therapeutix, Inc., 955 F.3d 194, 210, n.18 (1st Cir. 2020)("The district court correctly determined that [the defendant's] purchase of [the company's] shares during the class period somewhat '[f]urther negat[es] an inference of scienter.'"). Including Lucchino's acquisitions in the count, Lucchino's total disposition of his Frequency stock amounts to less than 15% of his total holdings, an amount that courts have

usually deemed insufficient to support scienter. Brennan v. Zafgen, Inc., 853 F.3d 606, 615-16 (1st Cir. 2017) (ruling that "insider trading allegations drifts toward the marginal end of that spectrum" when the insider's sales do not exceed 15% of his holdings); Archdiocese of Milwaukee Supporting Fund v. Investors Fin. Servs. Corp., 2007 WL 9797841, at *21 (D. Mass. July 31, 2007) (Dein, U.S.M.J.) (noting that the defendants' retention of a significant portion its holdings "suggest[s] that [the defendant] ha[s] every incentive to keep [the company] profitable," thereby undercutting the inference of scienter).

Quinones pushes back arguing that courts have found that sales of 2% of holdings were enough to support scienter. Pls.' Opp'n 16. To make their case, Quinones relies on Nursing Home and In re MicroStrategy. That reliance is misplaced. In Nursing Home, the court accepted that a sale of 2.1% sufficed to establish scienter solely because such a percentage constituted a "truly astronomical figure" -- $900,000,000. Nursing Home Pension Fund Loc. 144 v. Oracle Corp, 380 F.3d 1226, 1232 (9th Cir. 2004). There is not such an astronomical profit here. Similarly, In re MicroStrategy, the court ruled that a 2.1% sale sufficed because it generated profits in excess of $45,000,000 -- which in today's money would exceed $75,000,000 -- and amounted to a "significant dilution" of the defendant's control

power. In re MicroStrategy, Inc. Sec. Litig., 115 F. Supp. 2d 620, 646 (E.D. Va. 2000). Again, not so here.

In fact, there exists a much simpler explanation for Lucchino's decision to ramp up his sales: the price of Frequency stock steeply increased during the Class Period. As the complaint acknowledges "Lucchino's Class Period sales were . . . significantly more profitable." Compl. ¶ 15. Therefore, it is hardly surprising Lucchino decided to cash out at least some portion of his Frequency holdings. This further undermines an inference of scienter. Loc. No. 8 IBEW Ret. Plan v. Vertex Pharms. Inc., 140 F. Supp. 3d 120, 136 (D. Mass. 2015) (Saylor, J.), aff'd sub nom. Loc. No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharms., Inc., 838 F.3d 76 (1st Cir. 2016) ("[T]he portfolios of corporate insiders are often heavily weighted with the stock of the company. It is hardly surprising that such executives have a strong incentive to cash out at least some portion of their holdings when prices are high."); In re Wayfair, Inc. Sec. Litig., 471 F. Supp. 3d 332, 348 (D. Mass. 2020) (Woodlock, J.) ("[I]t would be perfectly natural for the defendants to sell their stock as share price increased; that they did so is not, on its own, material evidence of scienter.").

In addition, the absence of sales from any other Frequency insider during the Class Period further undercuts an inference of scienter. New Jersey Carpenters Pension & Annuity Funds v.

Biogen IDEC Inc., 537 F.3d 35, 56 (1st Cir. 2008)(citing Abrams v. Baker Hughes Inc., 292 F.3d 424, 435 (5th Cir. 2002) ("Noting that 'even unusual sales by one insider do not give rise to a strong inference of scienter' when other insiders had not engaged in suspicious trading during the class period.")); Id. (citing Ronconi v. Larkin, 253 F.3d 423, 436 (9th Cir. 2001) ("One insider's well timed sales do not support the 'strong inference' required by the statute where the rest of the equally knowledgeable insiders act in a way inconsistent with the inference . . . ."); see also Southland Sec. Corp. v. INSpire Ins. Solutions, Inc., 365 F.3d 353, 369 (5th Cir. 2004); San Leandro Emergency Med. Grp Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 814 (2d Cir. 1996); Acito v. IMCERA Group, 47 F.3d 47, 54 (2d Cir. 1995).

Quinones counters that the absence of sales from the other Frequency executives is evidence of scienter because it is "entirely reasonable for [Defendants] to refrain from selling stock during the Class Period to avoid the appearance of wrongdoing." Pls.' Opp'n 17 (citing Collier v. ModusLink Global Soloutions, Inc., 9 F. Supp. 3d 61, 74 (D. Mass. 2014) (Casper, J.). Quinones' argument is somewhat paradoxical and is devoid of merit. As a matter of principle, it is difficult to see how the act of refraining from engaging in an unlawful activity can be evidence that such activity took place. In fact, if the

absence of sales were evidence of scienter this would essentially reverse the burden of proving scienter and place it on the Defendants. This cannot be, as it is settled law that the burden lies with the plaintiffs. Simon v. Abiomed, Inc., 37 F. Supp. 3d 499, 523 (D. Mass. 2014) (Saylor, J.), aff'd sub nom. Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228 (1st Cir. 2015) ("Plaintiff bears the burden of demonstrating that sales by insiders were 'unusual or suspicious in amount or timing.'") (Citation omitted); Tharp, 321 F. Supp. 3d at 229 (citing Lirette, 27 F. Supp. 2d at 281 (A plaintiff "bears the burden of showing that sales by insiders were in fact unusual or suspicious in amount or timing.")). Moreover, the Collier opinion does little to advance Quinones' argument. In that case, the court limited itself to noting that the absence of insider trading did not conclusively undercut an inference of scienter based on other facts. Collier, 9 F. Supp. 3d at 73. Here the basis of the Quinones' scienter allegation is insider trading. Quinones' inability to plead sufficient facts showing that insider trading occurred undermines their position.

The timing of Lucchino's dispositions of stock is not suspicious. Quinones argues the opposite is true because most of the sales occurred after the alleged misrepresentations in October 2020 and January 2021. Pls.' Opp'n 16. Quinones also argues that Luchino's sales were "clumped around" specific

dates, which evinces the Defendants' intent to defraud investors. Pls.' Opp'n 17.

Quinones is incorrect and the authority they offer in support of their position contradicts them. It is true that most of the sales occurred after the allegedly misleading statements in October 2020 and January 2021. Pls.' Opp'n 17. These trades, however, occurred weeks after the statements. Id. In Wayfair -- the only case offered by Quinones to argue that Lucchino's sales timing is suspicious -- the court concluded that the timing was not suspicious even if some trades occurred on the day or days after the alleged misstatements. Wayfair, 471 F. Supp. 3d at 347. The court explained that the dates of the alleged misstatements were "not uniquely aligned with sales made by Defendants . . . [because] the defendants traded four or five days after each alleged misstatement." Id. By Quinones' own argument, Lucchino engaged in "10 separate sales in the month following the November 16, 2020 [announcement]" and "18 separate sales in the weeks following the January 11 and January 19, 2021 statements . . . ." Pls.' Opp'n 17. These trades were roughly evenly spread out through the Class Period; they were not "clumped around" specific dates as Quinones incorrectly alleges. McDonough Decl., Ex. 3, ECF No. 36-3. The table below aggregately summarizes Lucchino's sales during the Class Period:

Date(s)	Number of shares sold (aggregate)
11/2/2020	15,714
12/1/2020	15,714
12/7/2020-12/9/2020	27,028
12/14/2020-12/17/2020	41,662
1/4/2021-1/6/2021	61,690
1/27/2021	9,196
2/1/2021-2/3/2021	49,656
2/8/2021	16,554
3/1/2021	9,386

Id. It is also notable that, as shown by the table, most of Lucchino's sales occurred before the alleged misstatements of January 11 and January 19 2021. Had Lucchino sought fraudulently to profit on his sales, he would presumably have waited to make the bulk of his sales after those dates, when the price of Frequency stock peaked. This is not what Lucchino did. Hence, the timing of the sales can hardly be said to have "uniquely aligned" with the alleged misstatements.

In sum, Lucchino's sales during the Class Period are not suspicious in amount or timing and do not raise a strong inference of scienter.[3]

2. CW1's Statements Are Insufficient to Establish Scienter

Second, Quinones contends that CW1's statements raise a strong inference of scienter. The crucial passage of the complaint is set out below:

> CW1 also detailed how [Frequency] was aware of the self-selection and volunteer bias from the reports of "investigators"—i.e., the doctors responsible for administering the drug (or placebo) directly to patients and tracking them after treatment. CW1 said that many of the Phase 2a investigators had identified a concerning discrepancy between certain patient's responses during the screening process for admission and subsequent examinations by the investigators. Specifically, at screening, these patients informed the investigators that they could not hear certain sounds at varying decibel levels. Then, in subsequent examinations, they reported being able to hear those same sounds. According to CW1, several investigators contacted LeBel about this discrepancy to express their concerns to him. Again, CW1 worked directly with the investigators, even claiming to have a "very good relationship with all the physicians," so was in a position to know this information.

[3] The Defendants have devoted substantial efforts to argue that Lucchino's stock sale cannot establish scienter because they were made pursuant to an SEC Rule 10b5-1 plan. Defs.' Mem. 14-15. This Court disagrees. Lucchino's 10b5-1 plan is not public and has not been produced by Defendants. Nor have the Defendants provided alternative evidence that Lucchino's SEC Rule 10b5-1 plan "removed entirely from [his] discretion the question of when sales would occur, or that [he] we[s] unable to amend these trading plans." Mississippi Pub. Emps.' Ret. Sys., 523 F.3d at 92. Accordingly, this Court rejects the Defendants' argument.

Compl. ¶ 65 (emphasis added).

Contrary to what is urged by Quinones, this passage does not support a strong inference of scienter. The first problem with this passage is that it does not identify any conversation to which CW1 was privy. Rather, it relies on what unnamed investigators supposedly told LeBel to establish what LeBel knew. This "multi-layer hearsay" undercuts the inference of scienter. In re Vertex Pharms., Inc., Sec. Litig., 357 F. Supp. 2d 343, 353-54 (D. Mass. 2005) (Saris, J.) (discrediting confidential witness allegations based on multi-layer hearsay); In re iRobot Corp. Sec. Litig., 527 F. Supp. 3d at 141 (citing Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 996 (9th Cir. 2009), as amended (Feb. 10, 2009) ("Some courts have looked askance upon confidential sources that . . . 'report only [multi-layer] hearsay' . . . .").

Second, CW1's statement is insufficiently particularized to establish falsity. See In re Cabletron Sys., Inc., 311 F.3d 11, 29-30 (1st Cir. 2002) (whether facts provide an adequate basis for inferring scienter depends upon "an evaluation, inter alia, of the level of detail provided by the confidential sources . . . ."). All that CW1 asserts is that "several investigators" expressed "concerns" about a "concerning discrepancy" regarding the patients' ability to hear sounds at varying decibel levels. See Comp. ¶ 12. "[Adjectives and]

adverbs are not facts." Special Situations Fund III QP, L.P. v. Deloitte Touche Tohmatsu CPA, Ltd., 96 F. Supp. 3d 325, 344 (S.D.N.Y. 2015). Conspicuously missing in the complaint is any allegation that the discrepancy identified by the investigators is incompatible with Frequency's statement that every patient enrolled in the study had a meaningful recognition deficit. See Metzler Asset Management GmbH v. Kingsley, 928 F.3d 151, 162 (1st Cir. 2019) (noting that to find scienter "one would need to know . . . whether what [the defendant] learned was at odds with any of his . . . statements."). That some patients could not hear certain sounds at varying decibel levels and at subsequent examinations they reported being able to hear those same sounds does not establish that they did not possess a meaningful recognition deficit when they enrolled in the study -- let alone that this information was conveyed to LeBel. In fact, the complaint is devoid of any factual allegation that the investigators knew or even believed that some patients had successfully enrolled in the study despite not possessing the required meaningful word recognition deficit. Absent these crucial facts, this Court cannot draw a "strong" inference of scienter. In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d at 286 (a "statement that an unnamed person in no specified position of authority "made suggestions" . . . that [managers] may or may not have heard (or paid attention to) is a meager

fount for even a whiff of a fraudulent scheme, much less a particularization of its details.");

> The Complaint asserts that a confidential source formerly employed by Praecis "informed management that the pricing structure for Plenaxis was significantly flawed[]" . . . . Assuming it to be true that the source had so "informed management," more than that would be needed to support an allegation that "management" itself knew the structure to be flawed, as opposed to knowing simply that someone else (of unclear qualifications) thought that to be the case. The complaint thus deals in merely faux specificity. There are specific facts alleged, but those isolated facts, for all their concreteness, cannot support the broader conclusory allegations without help from other, missing facts.

In re Praecis Pharmaceuticals, Inc. Sec. Litig., 2007 WL 951695, at *19 n.14 (D. Mass. Mar. 28, 2007) (O'Toole, J.)

Third, Quinones is unable to identify when the supposed conversation between the investigators and LeBel occurred. Many courts have ruled such a failure to be fatal. Abiomed, Inc., 778 F.3d at 245 (ruling that the statements of several confidential witness failed to establish scienter because they "did not identify the time period to which most of their statements related."); In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016) (ruling no strong inference of scienter where complaint failed to plead "any specific facts about when the Defendants learned of the[ ] adverse events or even when the adverse events occurred."); Biogen IDEC Inc., 537 F.3d at 52-53 (discounting probative value of observations

by confidential sources in part because the sources did not disclose when those observations were made).

Attempting to circumvent this flaw in the complaint, Quinones argues that since "[p]atients were tracked weekly" and "Phase 2a started enrolling patients in October 2019 and completed enrollment by September 2020" then it is reasonable to infer that "most of the investigators' word recognition tests must have been completed before October 29, 2020." Pls.' Opp'n 9-10. From that, according to Quinones, it is possible to infer that the "Defendants knew of the bias in Phase 2a by at least October 29, 2020, when the first alleged misrepresentation occurred." Pls.' Opp'n 10. This is mere conjecture, which is not a substitute for well-pleaded facts. See Ganem, 845 F.3d at 457. For example, the complaint does not allege facts that would allow this Court to determine that most of the investigators' word recognition tests had been completed before October 29, 2020. What is missing is any allegation that most patients enrolled in the early phase of the study rather than closer to enrollment completion. Moreover, there is no allegation that would allow this Court to establish that a majority of studies completed before October 29, 2020, were conveyed to LeBel. Very simply, what if the concerning patients were among the minority that had yet to complete the study by October 29, 2020? Even assuming that it is possible to draw the

inference suggested by the plaintiffs, CW1's inability to identify when the supposed communication happened is an indication in and of itself of the unreliability of CW1's statement.

In sum, CW1's second-hand, unparticularized account of what an unnamed investigator supposedly told LeBel at an unspecified time cannot support a "strong" inference of scienter.

3. Quinones' "Core Operations" Argument Does Not Raise a Strong Inference of Scienter

Quinones argues that the importance of FX-322 to Frequency establishes an inference of scienter. Compl. ¶ 92.

Under the so called "core operations doctrine," "facts critical to a business's core operations . . . may be attributed to the company and its officers." Crowell v. Ionics, Inc., 343 F. Supp. 2d 1, 19 (D. Mass. 2004)(alteration and citation omitted). Courts, however, have refused to apply this doctrine absent "other significant evidence of a defendant's intent or recklessness, or a 'plus factor.'" In re Biogen Inc. Sec. Litig., 193 F. Supp. 3d 5, 51 (D. Mass. 2016) (Saylor, J.), aff'd, 857 F.3d 34 (1st Cir. 2017) (quoting In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d at 285); In re Psychemedics Corp. Sec. Litig., No. 17-10186, 2017 WL 5159212, 6 (D. Mass. 2017) (Stearns, J.) (ruling that "plaintiff's 'core operation' theory stands naked, unadorned by any other piece of evidence

purporting to establish the essential 'plus' factor -- guilty knowledge on the part of [the Defendants]").

Here, there is little doubt that FX-322 was central to Frequency's success. However, Quinones has failed to plead with particularity any plus factor that would allow this Court to consider their argument. Quinones' conclusory assertion that "there can be no doubt that Defendants knew of (or, at best, recklessly disregarded) that Phase 2a had been compromised by the enrollment of patients that did not meet the study's inclusion criteria," Compl. ¶ 92, certainly cannot be such a plus factor. Nor does Quinones' reliance on iRobot advance their case. Consistent with the jurisprudence referred to above, the iRobot court rejected the scienter allegations before it because the plaintiff had "fail[ed] to allege particularized facts as to [a] plus factor . . ." In re iRobot Corp. Sec. Litig., 527 F. Supp. 3d at 141. Put simply, the core operation doctrine cannot itself bootstrap an otherwise insufficient complaint above the high pleading standard imposed by the PSLRA. Given the absence of a plus factor here, Quinones' "core operation" argument fails.

4. The Non-Fraudulent Inference Is More Compelling

Ultimately, Quinones has failed to articulate a cohesive theory of fraud. According to Quinones, the facts alleged show that "the Defendants" were aware that not all study subjects had

meaningful hearing loss. Pls.' Opp'n 19. Rather than disclosing that information, they "effectively 'held their breaths' hoping the bias would not materialize while in the meantime Defendant Lucchino cashed in." Id.

A closer analysis of the facts alleged, however, reveals that this theory is unpersuasive. According to the complaint, it was LeBel, not Lucchino, who was contacted by the investigators about the alleged "concerning discrepancy." See Comp. ¶65. LeBel is not alleged to have sold any Frequency stock during the Class Period. This makes no sense. Had LeBel known that the prospects of Phase 2a were doomed, he would presumably have proceeded to sell his stock. Instead, the stock sales upon which Quinones relies to assert scienter were made by Lucchino, who is not alleged to have had any interactions with CW1 or the investigators. Nor are there any allegations that LeBel conveyed to Lucchino what he learned from his interactions with the investigators. The flaws in Quinones' theory are apparent.

Quinones attempts to plug these flaws by speculating that LeBel might have not been in a position to sell during the Class Period. See Pl.'s Opp'n at 17. Perhaps, LeBel's Frequency stock could have been restricted. But this argument does not hold much water. LeBel joined frequency in 2018 as the Company's CDO. Compl. ¶ 25. It is highly unlikely that he did

not own any unrestricted or partly unrestricted Frequency shares three years later in 2021.

The more compelling inference is that neither Lucchino nor LeBel were aware that patients had managed to elude their word recognition screening and to enroll despite not possessing the requisite word recognition deficit and, seeing the uptick in Frequency shares price, Lucchino decided to cash in a modest portion of his stock. This is not securities fraud. Therefore, the complaint does not survive the Defendants' motion to dismiss. See Brennan v. Zafgen, Inc., 199 F.Supp.3d 444, 471 (D.Mass., 2016)(Saylor, J.)(dismissing claims where "the fundamental theory of plaintiffs' case" was "unpersuasive").

III. CONCLUSION

Quinones has failed to plead sufficient facts to establish that the challenged statements are false and misleading, except for two. For those statements, however, Quinones has failed to allege sufficient facts to support a strong inference of scienter. Therefore, this Court **GRANTS** the Defendants' motion to dismiss.

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
JUDGE
of the

UNITED STATES[4]

[4] This is how my predecessor, Peleg Sprague (D. Mass. 1841-1865), would sign official documents. Now that I'm a Senior District Judge I adopt this format in honor of all the judicial colleagues, state and federal, with whom I have had the privilege to serve over the past 45 years.